

ATTACHMENT 30

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

**IN RE: DA VINCI SURGICAL ROBOT
ANTITRUST LITIGATION**

Lead Case No. 3:21-cv-03825-VC

THIS DOCUMENT RELATES TO:

All Actions

Rebuttal Expert Report of Dr. T. Kim Parnell

March 1, 2023

Highly Confidential – Subject to Protective Order

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testing. The use counter in no way detects that an instrument has been mishandled or misused, and does not prevent it from being damaged from such.

C. Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument.

1. To accurately establish a use limit or failure point, tests would need to actually test instruments to failure.

250. In my experience, studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur, all help to establish the potential range of life for an instrument. Establishing and identifying the potential failure modes accurately is extremely important.²⁷⁴ In the absence of this data and insight, one's ability to understand the EndoWrist system performance (especially the potential life) is limited. Intuitive primarily utilizes returned EndoWrists that are shown in the RMA log for failure analysis and root cause analysis. This data is useful, but many EndoWrists may never appear in the RMA data. For example, since there is no potential monetary credit for an EndoWrist with zero (0) lives remaining, many of these EndoWrists will be discarded rather than shipped to Intuitive. Some incentive is needed to get these EndoWrists for evaluation. As an example, in a sample of ten tested instruments, testing each to failure would involve setting certain failure conditions (such as breaks in instrument cables or dulled scissors) and observing at which point each of the instruments experiences a failure. In that ten-instrument sample, one instrument might fail at use 50, and nine others might fail after use 200.

²⁷⁴ See, e.g., "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." DNV, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvg-labs-hovik.html, and "Failure Analysis Testing: Engineering Failure Analysis |." Stress Engineering Services, Inc., 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/.

251. By contrast, halting tests after a certain number of uses produces skewed results. In the above example, if testing for the nine other instruments were arbitrarily halted at use 60, the results of the testing would indicate that the instruments had a lower acceptable life. Testing to failure produces a more accurate and insightful statistical analysis of instrument failures, because it actually establishes the range of failure conditions and the useful life of an instrument.

2. Intuitive testing is designed to validate target lives set by marketing and does not accurately assess the failure point for the instrument.

252. Intuitive life testing does not accurately assess the useful life of an instrument. Instead of attempting to establish the maximum number of lives that an instrument can be safely used, Intuitive's testing aims to statistically validate a preset target limit.

253. The initial targets for the Intuitive EndoWrist use counter are set by marketing, and help to support the Intuitive published revenue model.

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9 Q. Now, when Intuitive is first considering
10 what it's going to be setting the lives at,
11 marketing is involved in that process; right?

12 A. Marketing is involved to the extent that
13 they set goals for engineering.

14 Q. For example, marketing might set a goal of
15 ten lives for an instrument; right?

16 A. That's an example, yes.

17 Q. And then engineering would try to design an
18 instrument that would meet that ten-life goal;
19 right?

20 A. Yes.²⁷⁵

5 Q. But when a new instrument is being
6 developed for a customer, marketing is setting the

²⁷⁵ McGrogan depo. (*Rebotix*) tr., 35:9-20